

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Redegeld et al.

Serial No.: To be assigned

Filed: January 9, 2001

**For: INHIBITION OF PROTEIN BINDING
TO MAST CELLS**

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 4692US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EL740532412US

Date of Deposit with USPS: January 9, 2001

Person making Deposit: Adrina Miskin

Preliminary Amendment

Box Patent Application
Commissioner for Patents
Washington, D.C. 20231

Sir:

Before calculation of the filing fee, please amend the referenced application as follows:

IN THE SPECIFICATION :

Page 4, line 2, after “(AHWSGHCL)”, insert –SEQ ID NO: 1–;

Page 4, line 4, replace “labelled” with –labeled–;

Page 4, line 8, insert a comma after “invention”;

Page 4, line 9, insert a comma after “wherein” and “detection”;

Page 4, line 10, replace “labelled” with –labeled–;

Page 4, line 11, replace “labelled” with –labeled–;

Page 4, line 12, replace “labelled” with –labeled–;

Page 4, line 13, after “(AHWSGHCCCL)”, insert –SEQ ID NO: 1–;

Page 4, line 17, insert a comma after “of”;

Page 4, line 18, insert a comma after “respectively”;

Page 4, line 19, replace “labelled” with –labeled–;

Page 4, lines 22-23, replace “of reducing” with –to reduce–;

Page 4, line 25, replace “labelled” with –labeled–;

Page 4, line 27, replace “labelled” with –labeled–;

Page 4, line 28, replace “In cases like this it” with –It–;

Page 4, line 29, replace “occurs” with –occur–;

Page 4, line 32, replace “It goes without saying that the” with –The–;

Page 5, lines 13-14, replace “Applicant considers the possibility that migraine is also”
with –Migraines may also be–;

Page 5, line 16, replace “an advantageous” with –a preferred–;

Page 8, line 4, replace “foetal” with –fetal–;

Page 8, line 5, replace “FTIC-labelled” with –FITC-labeled–;

Page 8, line 11, replace “unlabelled” with –unlabeled–;

Page 8, line 20, replace “min.” with –minutes–;

Page 10, line 21, replace “sensitisation” with –sensitization–; and

Page 12, line 11, replace “Fig.” with –FIG.–.

IN THE CLAIMS:

3. (Amended) The compound of claim 1 [or 2], wherein the compound reduces the binding between the peptide and the free light chain of immunoglobulin by at least 10%[, preferably by at least 25%, more preferably by at least 50%, even more preferably by at least 75%, and most preferably by 90%].

4. (Amended) The compound of claim 2 [or 3], wherein the compound is a peptidomimeticum.

5. (Amended) The compound of claim 1 [according to any one of the preceding claims], wherein the compound is a pharmaceutically acceptable compound.

8. (Amended) The method according to claim [6 or] 7, wherein the test is based on fluorescence (de)polarization or internal energy transfer.

10. (Amended) A compound for use in treating a disease, said disease characterized by symptoms comprising:

- i) a concentration of the free light chain of immunoglobulin in serum of at least 8 mg/l[, in particular of at least 15 mg/l and more in particular 20 mg/l]; and/or
- ii) a concentration of the free light kappa-chain of immunoglobulin in spinal fluid of at least 70 $\mu\text{g/l}$, [in particular at least 100 $\mu\text{g/l}$, and more in particular 150 $\mu\text{g/l}$]; and/or
- iii) a concentration of the free lambda-chain of immunoglobulin in spinal fluid of at least 300 $\mu\text{g/l}$ [, in particular at least 400 $\mu\text{g/l}$, and more in particular 500 $\mu\text{g/l}$],

said drug comprising a compound according to claim 1 [any one of the claims 1 to 5, the compound obtained by using the method according to any one of the claims 6 to 9, Tamm-Horsefall glycoprotein (THP) and LC-binding peptide fragments thereof].

11. (Amended) The drug of claim 10, wherein the compound is a peptide or peptidomimeticum with a mass of less than 10 kDal[, preferably less than 2 kDal].

12. (Amended) The drug of claim 10 [or 11], wherein the disease is selected from the group consisting of asthma, allergy, chronic inflammatory bowel disorders, viral infection and multiple sclerosis.

13. (Amended) A pharmaceutical composition comprising a compound [according to any one of the claims 1 to 5 or obtained according to any one of the claims 6 to 9, or] selected from the group consisting of a compound that inhibits the binding of the free light chain of immunoglobulin to mast cells, wherein the compound, in the presence of an equimolar quantity of the free light chain of immunoglobulin, reduces binding between the free light chain of immunoglobulin and said mast cells by at least 5%, Tamm-Horsefall glycoprotein (THP) [or] and LC-binding peptides thereof

together with a pharmaceutically acceptable carrier or excipient.

Please add the following new claims:

16. The compound of claim 1, wherein the compound reduces the binding between the peptide and the free light chain of immunoglobulin by at least 25%.

17. The compound of claim 1, wherein the compound reduces the binding between the peptide and the free light chain of immunoglobulin by at least 50%.

18. The compound of claim 1, wherein the compound reduces the binding between the peptide and the free light chain of immunoglobulin by at least 75%.

19. The compound of claim 1, wherein the compound reduces the binding between the peptide and the free light chain of immunoglobulin by at least 90%.

20. The compound according to claim 3, wherein the compound is a peptidomimeticum.

21. The drug of claim 11, wherein the compound is a peptide or peptidomimeticum with a mass of less than 2 kDal.

22. A compound produced by the process comprising:

screening a series of compounds based on each compound's ability to bind the free light chain of immunoglobulin, wherein said screening comprises using a labeled compound capable of binding the free light chain of immunoglobulin and capable of competing with a peptide for binding to the free light chain of immunoglobulin;

performing a test comprising a competition reaction between at least one compound of said series of compounds and said peptide for binding to the light chain of immunoglobulin; and

selecting a compound from said series of compounds that inhibits binding between the peptide and the light chain of immunoglobulin.

23. The compound of claim 22, wherein the compound is a peptide or peptidomimeticum.

24. The compound of claim 23, wherein the compound has a mass of less than 10 kDal.

25. The compound of claim 23, wherein the compound has a mass of less than 2kDal.

26. A process for producing a compound having the ability to bind the free light chain of immunoglobulin, wherein the compound, in the presence of an equimolar quantity of the free light chain of immunoglobulin, reduces binding between the free light chain of immunoglobulin and mast cells by at least 5%, said process comprising:

screening a series of compounds based on their ability to bind the free light chain of immunoglobulin, wherein said screening comprises using a labeled compound capable of binding the free light chain of immunoglobulin and capable of competing with a peptide for binding to the free light chain of immunoglobulin;

performing a test comprising a competition reaction between at least one compound of said series of compounds and said peptide for binding to the light chain of immunoglobulin; and

selecting a compound from said series of compounds that inhibits binding between the peptide and the light chain of immunoglobulin.

27. The compound of claim 26, wherein the compound is a peptide or peptidomimeticum.

28. The compound of claim 27, wherein the compound has a mass of less than 10 kDal.

29. The compound of claim 27, wherein the compound has a mass of less than 2kDal.

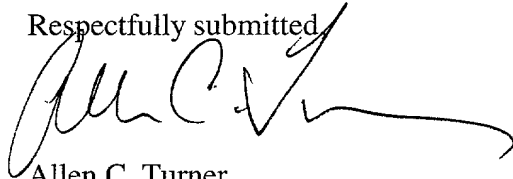
30. A method of treating a disease comprising:
administering the compound obtained by the method of claim 26.

Remarks

The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. All amendments were made to conform the claims to U.S. requirements. Applicants do not disclaim any subject matter in the claims and the amendments should not be construed as narrowing the subject matter of the claims.

If questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicants' representative at the address or telephone number below.

Respectfully submitted



Allen C. Turner

Registration No. 33,041

Krista Weber Powell

Registration No. P- 47, 867

Attorney for Applicants

TRASK BRITT, PC

P. O. Box 2550

Salt Lake City, Utah 84110-2550

Telephone: (801) 532-1922

Date: January 9, 2001